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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 10/803,345   | 03/18/2004  | Rae Ellen Syverson   | KCC 4749.2 (K-C<br>16,858.2)  | 5820             |
| 321  | 7590        | 12/01/2006           | EXAMINER                      |                  |
| SENNIGER POWERS<br>ONE METROPOLITAN SQUARE<br>16TH FLOOR<br>ST LOUIS, MO 63102 |             |                      | CHANNAVAJJALA, LAKSHMI SARADA |                  |
|  |             |                      | ART UNIT                      | PAPER NUMBER     |
|  |             |                      | 1615                          |                  |

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                     |  |
|------------------------------|--------------------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>               | <b>Applicant(s)</b> |  |
|                              | 10/803,345                           | SYVERSON ET AL.     |  |
|                              | Examiner<br>Lakshmi S. Channavajjala | Art Unit<br>1615    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 August 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 12, 13 and 21 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 11, 14-20, 22-32 and 48-62 is/are rejected.
- 7) Claim(s) 33-47 and 63-68 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

Receipt of terminal disclaimer and response dated 8-17-06 is acknowledged. Claims 1-68 are pending. Claims 2-10, 12, 13 and 21 are withdrawn as non-elected and claims 1, 11, 14-20 and 22-68 are considered for examination.

The terminal disclaimer filed on 8-17-06 has been reviewed and is accepted.

The terminal disclaimer has been recorded.

***Response to Arguments***

Applicant's arguments filed 8-17-06 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 103***

1. Claims 1, 11, 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 1204777 in view of D'Augustine.

DE teaches synergistic increase of the bactericidal potency of hexachlorophene by the addition of benzoic acid, aniline or benzamide. In particular, DE teaches that benzamide (reads on instant claimed species) increased the germicidal activity against *Staphylococcus aureus*. DE does not teach the use of benzamide with the claimed articles.

D'Augustine teaches a method for treating intravaginal or transvaginal bacterial, fungal, viral or parasitic infections comprising a device that contains a pharmaceutically effective amount of an antimicrobial, antifungal, antiviral or antiparasitic agent.

D'Augustine teaches the device in the form of a non-absorbent tampon or tampon-like

device, intravaginal sponge or ring etc (col. 2, summary of invention, col. 3 & col. 7, lines 1-29, brief description of figure 15). D'Augustine teaches addition of a number of antimicrobial compounds depending on the infection to be controlled in and around vagina. D'Augustine does not teach the claimed compound.

Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the staphylococcus inhibiting benzamide of DE on the intra or transvaginal articles such as tampons or vaginal sponge etc., of D'Augustine, in appropriate amounts to inhibit the *S. aureus* infections in and around the vagina because D'Augustine suggests that the delivery of the desired drugs to the vaginal mucosa and vaginal epithelium is effective with the local application of the antimicrobial drugs present on the articles than when administered systemically. Further, optimizing the amount of benzamide on the article, depending on the article (tampon, sponge, ring etc.,) so as to achieve the antimicrobial effect with a minimum amount of the antimicrobial.

**RESPONSE:** Applicants present the same arguments of 2-27-06 that were addressed in last office action dated 5-17-06, which are reproduced below: Applicants argue that DE teaches benzamide to increase the bactericidal activity of hexachlorophene by adding 50% to 91% by weight of hexachlorophene to increase the activity against *S. aureus* by 37% to 100%. It is argued that DE fails to teach non-absorbent substrates of the instant claims, for insertion in to vagina. However, the instant rejection is made over a combination of references and the teaching of D'Augustine has been relied upon for the claimed non-absorbent materials.

Applicants argue that the combination of the teachings of D'Augustine i.e., the use of vaginal devices and antibacterial, antifungal or antiviral composition for treating vaginal infections, does not meet the requirements for establishing *prima facie* obviousness, without the blue print of applicants' disclosure. Applicants argue that the motivation to combine the above references is not convincing as to why one skilled in the art would pick the composition of DE over all of the other toxic, antibacterial compositions of the art, when D'Augustine describes numerous suitable antibacterial compositions to use with their non-absorbent devices. Applicants arguments are not persuasive because DE suggests a synergistic increase in the antibacterial activity by the addition of compounds such as benzamide, aniline etc., which is a very small group of group of compounds as opposed to the argument that DE suggests numerous other compounds. On the other hand D'Augustine teaches antibacterial compounds but does not teach the highly synergistic effect in treating bacterial infection, which is suggested by DE. Applicants' argument that DE is silent about the use of benzamide on intra-vaginal devices is not persuasive because the motivation to employ the benzamide on the claimed devices comes from the teaching of D'Augustine, which describes several bacterial infections that occur in vaginal area.

Applicants argue that while DE recognizes benzamide as a antibacterial agent, the first active ingredient of the instant claims is an used as an exoprotein inhibitor and not an antibacterial agent without seeking to kill the bacterial as the killing is non-selective that includes killing good bacteria in the vaginal area and is thus harmful. Applicants' arguments are not persuasive because instant claims do not exclude killing

of the bacteria while inhibiting exoprotein inhibition. Instant claims also fail to recite the limitation that the "good" bacteria should not be killed. Further, even though the references cited recognize antibacterial effect, it is to be noted that the while the ultimate effect of an antibacterial agent is killing the bacteria, such an effect includes inhibiting proteins. Thus, the antibacterial teaching of DE is inclusive of inhibiting exoprotein.

2. Claims 1, 11, 14-20 and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,612,045 to Syverson et al ('045) in view of DE 1204777 (DE).

'045 teach articles such as tampons comprising an effective amount of an ether compound in an amount sufficient for inhibiting the production exoprotein by Gram-positive bacteria (claim 1, Table I). The ether compounds of '045 are the same as that claimed in the instant invention (claims and specification). '045 suggest combining other pharmaceutical adjuncts such as anti-inflammatories, antibacterial compounds etc., with the ether compounds, but fails to teach the claimed benzamide.

DE teaches synergistic increase of the bactericidal potency of hexachlorophene by the addition of benzoic acid, aniline or benzamide. In particular, DE teaches that benzamide (reads on instant claimed species) increased the germicidal activity against *Staphylococcus aureus*. DE does not teach the use of benzamide with the claimed articles.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine the benzamide of DE with the toxin inhibiting

ether compounds of '549 and apply to the articles such as feminine napkins or tampons because '549 teach feminine hygiene products coated with antimicrobial agents such as ether for the inhibition of exoprotein (toxin) by Gram positive bacteria and DE also teaches benzamide for *S. aureus* inhibition, constituting analogous art. Accordingly, a skilled artisan would have expected a synergistic increase inhibition of exoprotein production by benzamide and ether compounds. Further, optimizing the amounts of amounts of benzamide on the articles of '549 so as to achieve the desired antimicrobial effect would have been within the scope of a skilled artisan. While the Syverson does not specifically state non-absorbent articles, absent any unexpected results with respect to the non-absorbency of the articles, it would have been within the scope of a skilled artisan to use either a non-absorbent or absorbent article for incorporating the above antimicrobial compounds and still achieve the same effect.

**RESPONSE:** Examiner clarifies that the instant rejection includes claim 32, which was previously (office action 11-28-05) indicated as being allowable and claims 33-47 and 63-68 are allowable. Applicants present the same arguments of 2-27-06 that were addressed in last office action dated 5-17-06, which are reproduced below:

Applicants present the same arguments with respect to the teachings of DE. Applicants argue that the office failed to meet its burden to establish *prima facie* case of obviousness. It is argued that the cited references do not teach the non-absorbent substrate claimed, and that '045 is directed to employing ether compounds that can be used with absorbent articles such as catamenial tampons to inhibit the exoprotein of Gram positive bacteria, more specifically to solve the problem of TSST-1 produced by

*S. aureus*. It is argued that '045 do not teach benzamide and that DE does not teach that benzamide can be used safely for humans. Applicants' arguments are not persuasive because the motivation to use benzamide of DE in the intra-vaginal devices comes from the teachings of '045, which also teaches infections and the toxic conditions caused by the same organism *S. aureus*. '045 further teaches that the compounds effective against *S. aureus* can be used in combination with compounds such as ether be used on absorbent as well as non-absorbent fibers of the devices, such as covers or wrappers of the vaginal devices including tampons (col. 3, lines 55-60). Thus, '045 clearly suggest a rationale for employing compounds effective against *S. aureus* on absorbent as well as non-absorbent articles. If applicants' argument that benzamide would unavoidably and inevitably could harm the sensitive mucosal membrane of inner vagina, then the same argument should hold true for the claimed invention because instant invention also employs the same benzamide.

3. Claims 1, 11, 14-20 and 48-55 are rejected as being unpatentable over US 5,685,872 ('872) to Syverson in view of DE 1204777.

'872 teach articles such as a tampon or feminine hygiene pad comprising an effective amount of active agents such as disodium lauramphodiacetate, lauramide monoethanolamine etc., for inhibiting the exoprotein production by Gram-positive bacteria (see abstract and table II). '872 fail to teach benzamide.

DE teaches synergistic increase of the bactericidal potency of hexachlorophene by the addition of benzoic acid, aniline or benzamide. In particular, DE teaches that

benzamide (reads on instant claimed species) increased the germicidal activity against *Staphylococcus aureus*. DE does not teach the use of benzamide with the claimed articles.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine the benzamide of DE with the toxin inhibiting ether compounds of '872 and apply to the articles such as feminine napkins or tampons because '872 teach feminine hygiene products coated with antimicrobial agents such as ether for the inhibition of exoprotein (toxin) by Gram positive bacteria and DE also teaches benzamide for *S. aureus* inhibition, constituting analogous art. Accordingly, a skilled artisan would have expected a synergistic increase inhibition of exoprotein production by benzamide and ether compounds. Further, optimizing the amounts of amounts of benzamide on the articles of '872 so as to achieve the desires antimicrobial effect would have been within the scope of a skilled artisan. While the Syverson does not specifically state non-absorbent articles, absent any unexpected results with respect to the non-absorbency of the articles, it would have been within the scope of a skilled artisan to use either a non-absorbent or absorbent article for incorporating the above antimicrobial compounds and still achieve the same effect.

**RESPONSE:** Applicants present the same arguments of 2-27-06 that were addressed in last office action dated 5-17-06, which are reproduced below:

Applicants present same arguments with respect to the teachings of DE. Applicants argue that the office failed to meet its burden to establish *prima facie* case of obviousness. It is argued that the cited references do not teach the non-absorbent

substrate claimed, and that '872 is directed to employing compounds that can be used with absorbent articles such as catamenial tampons to inhibit the exoprotein of Gram positive bacteria, particularly for toxic shock syndrome caused by *S. aureus*. It is argued that '872 do not teach benzamide or using the compounds on non-absorbent articles as claimed, and that DE does not teach that benzamide can be used safely for humans. Applicants' arguments are not persuasive because the motivation to use benzamide of DE in the intra-vaginal devices comes from the teachings of '872, which also teaches infections and the toxic conditions caused by the same organism *S. aureus*. '872 further teaches that the compounds effective against *S. aureus* can be used in combination with compounds such as ether be used on absorbent as well as non-absorbent fibers of the devices, such as covers or wrappers of the vaginal devices including tampons (paragraph bridging col. 3 and col.4). Thus, '872 clearly suggest a rationale for employing compounds effective against *S. aureus* on absorbent as well as non-absorbent articles. If applicants' argument that benzamide would unavoidably and inevitably could harm the sensitive mucosal membrane of inner vagina, then the same argument should hold true for the claimed invention because instant invention also employs the same benzamide.

4. Claims 1, 11, 14-20 and 56-62 are rejected as being unpatentable over US 5,618,554 to Syverson ('554) in view of DE 1204777.

'554 teach articles such as a tampon or feminine hygiene pad comprising an effective amount of active agents such as lauramine, lauraminopropionic acid etc., as

preferred active agents, for inhibiting the exoprotein production by Gram-positive bacteria (see abstract and table II).

DE teaches synergistic increase of the bactericidal potency of hexachlorophene by the addition of benzoic acid, aniline or benzamide. In particular, DE teaches that benzamide (reads on instant claimed species) increased the germicidal activity against *Staphylococcus aureus*. DE does not teach the use of benzamide with the claimed articles.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine the benzamide of DE with the toxin inhibiting ether compounds of '554 and apply to the articles such as feminine napkins or tampons because '554 teach feminine hygiene products coated with antimicrobial agents such as ether for the inhibition of exoprotein (toxin) by Gram positive bacteria and DE also teaches benzamide for *S. aureus* inhibition, constituting analogous art. Accordingly, a skilled artisan would have expected a synergistic increase inhibition of exoprotein production by benzamide and ether compounds. Further, optimizing the amounts of amounts of benzamide on the articles of '554 so as to achieve the desired antimicrobial effect would have been within the scope of a skilled artisan. While the Syverson does not specifically state non-absorbent articles, absent any unexpected results with respect to the non-absorbency of the articles, it would have been within the scope of a skilled artisan to use either a non-absorbent or absorbent article for incorporating the above antimicrobial compounds and still achieve the same effect.

**RESPONSE:** Applicants present the same arguments of 2-27-06 that were addressed in last office action dated 5-17-06, which are reproduced below:

Applicants present same arguments with respect to the teachings of DE. It is argued that DE fails to teach second active agent or the non-absorbent device of the instant claims. Applicants argue that the office failed to meet its burden to establish *prima facie* case of obviousness. It is argued that the cited references do not teach the non-absorbent substrate claimed, and that '554 is directed to employing nitrogen containing compounds that can be used with absorbent articles such as catamenial tampons to inhibit the exoprotein of Gram positive bacteria, more specifically to solve the problem of TSST-1 produced by *S. aureus*. It is argued that '554 do not teach benzamide and that DE does not teach that benzamide can be used safely for humans. Applicants' arguments are not persuasive because the motivation to use benzamide of DE in the intra-vaginal devices comes from the teachings of '554, which also teaches infections and the toxic conditions caused by the same organism *S. aureus*. '554 further teaches that the compounds effective against *S. aureus* can be used in combination with compounds such as ether be used on absorbent as well as non-absorbent fibers of the devices, such as covers or wrappers of the vaginal devices including tampons. Thus, '554 clearly suggest a rationale for employing compounds effective against *S. aureus* on absorbent as well as non-absorbent articles. If applicants' argument that benzamide would unavoidably and inevitably could harm the sensitive mucosal membrane of inner vagina, then the same argument should hold true for the claimed invention because instant invention also employs the same benzamide.

***Allowable Subject Matter***

Claims 33-47 and 63-68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims because employing the combination of compounds claimed in the claims 33-47 and 63-68 (i.e., benzamide, ethers and the compounds of the instant claims 33-47 and 63-68) on the claimed non-absorbent articles are not obvious from the teachings of the prior art.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 1615  
November 26, 2006



LAKSHMI S. CHANNAVAJJALA  
PRIMARY EXAMINER